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SPECIAL REPORT

Reform of Risk Regulation: Achieving More Protection at Less Cost

Report of the Harvard Group on Risk Management Reform

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PREFACE

The Harvard Group on Risk Management Reform was established in 1994 by the Center for Risk Analysis at the Harvard School of Public Health. The origins of the Group reside in discussions several years ago about the need for reform of risk regulation.

In the spring of 1992, the Bush Administration began development of a new presidential executive order aimed at bringing more scientific rigor and political accountability to the process of health, safety, and environmental regulation. At the time, I was asked by the Counsel to President Bush, C. Boyden Gray, to provide advice on the development of the executive order. My basic concern, shared by Mr. Gray, was that the regulatory process seemed to be overreacting to small and speculative risks while leaving larger and more certain risks unattended. The insights that could have been provided by the emerging science of risk analysis seemed to be poorly used by federal regulatory agencies. The stakes were large: unnecessary death and illness, preventable harm to the natural environment, and wasted economic resources.

A political judgment was made in the summer of 1992 that such a far-reaching reform should not be launched in the middle of a Presidential election campaign. After the election, the momentum for reform of risk regulation was not lost. In 1993 President Clinton issued an executive order on regulatory planning and review that gave some attention to the need for sound risk assessment and cost-benefit analysis. Congress also began to express serious interest in the issue. In particular, Senators Bennett Johnston and Daniel Patrick Moynihan, as well as several members of the House, began introducing bills on this issue.

In 1993 I approached Mr. Gray, who had returned to the practice of law at Wilmer, Cutler and Pickering, about the need for systematic thinking about how the process of risk regulation should be reformed. Mr. Gray agreed to work with me in an effort to identify a distinguished group of scholars and practitioners who might collaborate with us in the design of a solution. The Harvard Center for Risk Analysis (HCRA), whose mission is to promote reasoned public responses to health, safety, and environmental hazards, served as sponsor of the Group and a technical resource on the scientific aspects of risk analysis.

With the assistance of Mr. Gray, HCRA received a grant from the Lynde and Harry Bradley Foundation to convene the Group. Our goal was to devise a concrete set of recommendations that Congress and the President might consider in their deliberations about regulatory reform.

From the outset, HCRA was not interested in a project whose progress would be constrained by the interests of stakeholders. Instead, HCRA convened a group of experts who we felt had the courage and wisdom to call for careful yet major surgery on the federal government's process of risk regulation. When we invited the experts to join us, we did not know whether they all shared our basic convictions about the issue. We worked together diligently, including a one-day meeting in August 1994, a two-day meeting in Miami in January 1995, and an extensive period of iterations on this final report.

The Group operated on the basis of consensus, recognizing that differing points of view might emerge and some supplementary statements by individuals might be appropriate (several such statements are included in the Appendix to this report). Much to our surprise, the Group came to a shared conclusion that even more substantial reforms are necessary than those Mr. Gray and I had envisioned in 1992. Although each member of the Group may not endorse every statement in the report, there is consensus behind the four major recommendations that are offered.

In the process of producing the report, we received significant technical and organizational assistance from selected faculty, advisors, staff, and students at the Harvard Center for Risk Analysis. Ms. March Sadowitz of the Center was the determined force that made the project happen. Intellectually, the project received a major boost from Jonathan Wiener, an attorney who had worked in both the Bush and Clinton Administrations and who is also a member of the advisory committee to the Harvard Center for Risk Analysis. At important junctures in the project, we also received a helpful hand from my faculty colleague Professor Marc Roberts, who urged us to recognize the limits of formal risk analysis, and from doctoral student Nancy Beaulieu, who urged us not to forget considerations of equity in our pursuit of efficiency.

As important as these contributions were, we owe our greatest debt to the fifteen senior members of the Harvard Group on Risk Management Reform who, led by C. Boyden Gray, hammered out a new vision of risk regulation that promises to be more effective and less costly than the system America has today. Although many important details about our proposals need to be worked out, we hope that the ideas contained in this brief report will make a useful contribution to public deliberations about how to better protect public health and the environment in a cost-effective manner.

John D. Graham, Ph.D.
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INTRODUCTION

The role of federal regulatory agencies in protecting citizens from risks to human health, safety, and the environment has increased dramatically in the last thirty years. Agencies such as the Consumer Product Safety Commission, the Environmental Protection Agency, the Federal Aviation Administration, the Food and Drug Administration, the Food Safety and Inspection Service, the National Highway Traffic Safety Administration, the Nuclear Regulatory Commission, and the Occupational Safety and Health Administration have far-reaching legal powers. As they pursue their mandates to make life safer and healthier for citizens and, in the case of environmental regulation, for plant and animal species, they can restrict the day-to-day behaviors of businesses, states, localities, and private citizens.

The direct cost to taxpayers of operating these agencies is modest (less than $15 billion per year),[1] a small fraction of the large budgets of the Department of Defense and the Department of Health and Human Services. However, regulatory agencies impose large economic costs on state and local governments and the private sector.

Precise figures on the amount of "induced" regulatory costs are unavailable, but federal risk regulations are believed to be responsible for the majority of the nation's estimated $600 billion annual bill for regulatory costs — a burden that translates into about $6,000 per year per household. The fastest growing segment of regulatory costs derives from implementation of laws and regulations aimed at environmental protection.[2]

There are, however, substantial benefits from federal risk regulation. While these benefits are not easy to quantify in dollars, one study estimates that annual benefits of "social" regulation may be as high as $200 billion per year.[3] For example, over the past thirty years the United States has made substantial progress in cleaning up air, water and land, in part due to the strong regulatory presence of the federal government.[4] The automobile manufacturing industry is now producing cars that emit 75-95% fewer pollutants from tailpipes than they did in 1968 — a rate of progress that would not have been achieved without strong federal regulation.[5] Prevention of lead pollution has been a notable success story, as the national rate of lead emissions from all man-made sources has declined 96% since 1970,[6] and the concentrations of lead in the blood of children have fallen substantially, particularly since the lead content of gasoline was reduced and then eliminated.[7] Product manufacturers have also responded to regulatory and liability pressure by paying more attention to safety in both design and manufacturing.[8] Many new cost-effective safety features have been added to products (e.g., airbags in automobiles) as a result of the continued prodding and regulatory presence of the federal government.[9] One of the largest public health successes has been the federal government's concerted campaign to inform the public of the risks of smoking, which has resulted in a sharp decline in the number of adults who smoke (though much more needs to be done).[10] In short, many risk-reduction policies have been shown to have benefits greater than costs, even though benefits are sometimes difficult to estimate.[11]

Unlike the trend to deregulation that has achieved some success in the economic sphere (e.g, in the telecommunications industry), complete elimination of risk regulation is not a desirable course and has few serious advocates. The emerging consensus is, however, that risk regulation can be made more effective and less costly without becoming less democratic or less equitable. As society moves to higher levels of risk reduction and spends more resources to protect health and the environment, the marginal or incremental costs of achieving additional safety can become very large. This presents an opportunity for Congress and the President to make dramatic improvements in overall regulatory performance by making sure that priorities are sound and regulations are cost effective.

THE NEED FOR REGULATORY REFORM

Federal risk regulation has never been systematically reviewed. Congress began to enact the key enabling laws beginning in the New Deal, and significantly expanded their scope in the late 1960's and early 1970's. Yet Congress has never passed any legislation dealing comprehensively with risk. Many reform opportunities have been

identified by such diverse sources as the Clinton-Gore Administration,[12] the Carnegie Commission,[13] the Business Roundtable,[14] Supreme Court Justice Stephen Breyer,[15] and experts at Resources for the Future,[16] the American Enterprise Institute,[17] the Brookings Institution,[18] the National Research Council,[19] and independent scholars at universities throughout the country.[20]

In this report we do not review in detail the well-documented need for reform but instead emphasize what we regard as the fundamental problem: the misallocation of resources that may result from current approaches to risk analysis and regulation. Later, in our discussions of recommendations, we explain which specific defects in the current system will be addressed by each recommendation.

If resources were not limited, federal agencies could be expected to tackle every health, safety, and environmental hazard. Since resources are certainly not unlimited, and may prove to be more constrained in the years ahead than they are now, risks need to be ordered in priority for regulatory action. The current regulatory priorities of the federal government can be improved by being more firmly rooted in sound science and thoughtful value judgements.

For example, in the late 1980's and early 1990's, experts working with EPA ranked the major environmental hazards facing this country. They found little correlation between the laws and appropriations passed by Congress and the "high-risk" dangers as seen by risk managers and experts from the scientific community.[21] While the speculative risk from human exposure to abandoned toxic waste dumps was a high priority in Congress, experts were more concerned about the potential adverse consequences of habitat destruction and global climate change. In a recent speech at Harvard, former EPA Administrator William Reilly commented with pride (and frustration) that the fraction of EPA's budget devoted to "high-risk" threats increased from 15% to 30% during his four-year tenure as Administrator. He emphasized that the Congress needs to take a serious look at the priorities of EPA if further progress is to be made.[22]

Such sweeping comparisons of diverse risks are not based on application of a common numerical metric such as lives lost or dollars wasted. They are based on a mix of scientific and value judgments. Expert judgements are known to be fallible, particularly when experts stray from their particular field of expertise.[23] Note that the potential hazards of abandoned waste sites and global warming differ not only in their scientific plausibility but also in the number of people that might be affected, the type of adverse effects that might occur, and the time scale of the postulated adverse effects. Some degree of skepticism about such broad comparisons of complex hazards is warranted, but more targeted risk comparisons also suggest that questionable regulatory priorities are widespread.

Here are just a few examples from the vast literature on risk management. More regulatory attention is given to the hazards of eating tiny amounts of pesticide residues on fruits and vegetables than to the health of farmworkers and pesticide applicators, who incur larger exposures to pesticides.[24] More generally, low levels of exposure to animal carcinogens in the environment receive greater regulatory priority than much higher levels of exposure to carcinogens in the workplace.[25] Government devotes more effort regulating outdoor air than indoor air, even though

people spend more time indoors and concentrations of pollutants are greater indoors.[26] The remote possibility of children ingesting lead in soil at outdoor industrial waste sites is a major concern in EPA's Superfund program while the lead in house dust now being ingested by millions of children is only beginning to be addressed.[27] The recent health concerns about the presence of asbestos in school buildings, a relatively minor and speculative hazard to children, have received a disproportionate share of governmental attention compared to more serious dangers in schools such as the risk of contracting AIDS from intravenous drug use, unprotected sexual behavior and traumatic injury from accidents and violence.[28] Some type of counterargument can be made about each of these examples but these are indications that regulatory priorities can be improved.

If priorities were better set, risk regulation could be made more protective, without increasing the overall cost of regulation. A recent study examined 200 programs designed to advance human health in the United States. Some highly cost-effective programs were not fully implemented (e.g., childhood immunization against mumps, measles and rubella) while other highly cost-ineffective programs were widely implemented (e.g., control of low-level exposures to chemicals emitted into the air from factories). The study estimated that a reallocation of resources to more cost-effective programs could save an additional 60,000 lives per year at no increased cost to taxpayers or the private sector. Alternatively, the country could save the same number of lives we are currently saving but do so at a $31 billion annual saving to taxpayers and the private sector.[29]

This kind of information is by no means definitive or exhaustive. For example, the study cited above contains no information about nonfatal diseases and injuries, quality of life, or risk to ecosystems. Nor are we suggesting that tangible outcomes should be the sole basis for regulatory policy. Policy makers should also be influenced by important subjective factors such as whether risks are controllable by individuals through personal actions, whether risks are potentially catastrophic or irreversible in their consequences, and whether risks and associated benefits are fairly distributed among citizens.[30] A growing number of states and localities are incorporating these kinds of considerations into risk-ranking projects that are used by governors and mayors to set priorities. These projects are also finding evidence of missed opportunities in the current risk-protection priorities of government.[31]

It is not plausible to think that existing risk regulation reflects a considered democratic judgement about the best way for government to proceed. Since the public lacks information about many risks, and because it is not in a good position to compare risks against one another, it cannot be held responsible for the absence of good priority setting.[32] Sometimes risk regulation appears to be a response to sensationalistic anecdotes, or to interest-group pressures, rather than to deliberative judgments by the public about priorities for risk management.[33] In any event, structural changes are necessary to allow better public assessment of what the government is doing and how priorities are set.

Nor are these priority-setting problems being tolerated in order to protect the interests of disadvantaged populations such as the poor and people of color. Regulatory inefficiencies often hurt disadvantaged populations. Some of the most

significant risks incurred by disadvantaged citizens would certainly rank high in any overall ranking of risks (e.g., diseases from poor nutrition, the persistent problems of smoking and alcohol abuse, the daily incidents of violence in homes and communities, and childhood lead poisoning from ingestion of deteriorating lead paint in older homes). Such risks do not receive sufficient governmental priority precisely because the limited political power of disadvantaged populations is not counteracted by the use of comparative risk analysis. Thus, bringing more scientific rigor and thoughtful value judgments to risk regulation is important precisely because this can focus attention on serious risks that are experienced disproportionately by disadvantaged citizens.

Sometimes when agencies focus on what seem to be questionable priorities, the responsibility rests with previous decisions made by the Congress. For example, Congress has passed several laws that overtly prohibit regulators from achieving a reasonable relationship between the costs of their actions and the benefits. Examples of laws that preclude benefit-cost balancing include the Delaney Clause enacted under the Federal Food, Drug, and Cosmetic Act and the primary ambient air quality standards set under section 109 of the Clean Air Act. When agencies are forced to regulate some risks too stringently, they are induced to neglect a larger array of risks that could be reduced significantly at modest cost to the public.[34] Laws that mandate zero risk or that preclude benefit-cost balancing become highly dysfunctional in practice.[35]

In other cases, distorted priorities may be induced by the kinds of risk information that agencies present to Congress and the public. The risk assessment practices of agencies are not always based on the best available scientific information. For example, agencies have been slow to revise their risk assessments of unleaded gasoline, benzene, chloroform and formaldehyde in light of new evidence suggesting that low levels of exposure may not be as harmful as previously thought.[36] Yet these chemicals are regulatory priorities under federal environmental laws such as the Clean Air Act and the Safe Drinking Water Act. On the other hand, a case can be made that agencies have not responded rapidly enough to a growing body of evidence suggesting that fine particles are more harmful at relatively low levels of exposure than previously thought.[37] The need for agencies to pay special attention to subgroups of the population such as children has also been emphasized in recommendations to the federal government.[38] The challenge for federal agencies to keep pace with advances in science, while maintaining a predictable regulatory process, has been recognized for years but remains a problem.[39]

Reasonable questions have also been raised about whether agency analysts — who must make assumptions when the science is incomplete or ambiguous — explain adequately the sensitivity of their risk estimates to plausible changes in assumptions.[40] When numerical risk estimates are reported without a clear statement about uncertainties, the numbers can be misleading to policymakers who are responsible for setting regulatory priorities.[41] When seemingly precise risk estimates are publicized based on assumptions, it is not always apparent that alternative default positions could have been made, that some are scientifically more

plausible than others, and that Congress has only rarely specified a default position in statute.[42] The subtle yet important differences in the assumptions made in radiation versus chemical risk assessment are a particular cause for confusion among policymakers.[43]

As Congress considers legislation to promote the role of risk comparison and risk-based priorities in regulation, it will become even more important that agency risk estimates are produced in a manner that explains what is known and not known and what the implications of alternative assumptions might be. Since the emerging tool of risk assessment will play a central role in any effort to bring more science to regulatory priorities, it is critical that policy makers recognize the importance of strengthening agency risk assessment processes while being aware of the limitations of this analytical tool.[44]

RECOMMENDATIONS

How, precisely, are the laudable objectives of regulatory reform (more effectiveness in risk reduction at less cost without aggravating problems of inequity) to be achieved? The solution is certainly not straightforward, since if that were the case previous reform efforts would have been successful.

In order to answer this question, elected officials will need to embrace an unusual combination of legislative reforms that do not fit neatly in normal partisan or ideological perspectives. Indeed, we believe the solution rests in providing both more and less power to the federal government; in placing both more and less confidence in the technical tools of risk analysis; and in entrusting more flexibility to local governments and private firms which historically have been significant sources of pollution and other kinds of risks.

RECOMMENDATION #1: **Congress should authorize the President's science advisor to lead, integrate, and oversee the assessment and ranking of health, safety, and environmental risks in collaboration with federal agencies responsible for risk regulation.**

The United States Congress should pass legislation centralizing leadership of the assessment and ranking of risks in the Office of Science and Technology Policy of the Executive Office of the President. This realignment of oversight responsibility should be accompanied by risk-assessment guidelines issued by OSTP requiring agencies to use sound science, to fully disclose important assumptions and major points of uncertainty, and to establish procedures for public participation and scientific peer review of guidelines and specific assessments. The OSTP guidelines are intended to stimulate development of tailored guidelines within individual programs and agencies, where the technical responsibility to conduct risk assessments and rankings should reside. Under OSTP's leadership, a systematic process of risk-based priority setting should be established within each agency while a major OSTP-sponsored experiment in risk ranking is undertaken for a sample of diverse risks that span the jurisdictions of several agencies. Since useful rankings

require thoughtful value judgments as well as sound scientific information, the OSTP guidelines should assure that ordinary citizens as well as scientific experts participate in risk-ranking exercises sponsored by the federal government. A Director of Risk Analysis, appointed by the President with Senate confirmation, should be created to lead the new division in OSTP. Congress should appropriate the funding necessary for OSTP to fulfill this new role.

DISCUSSION

Currently, risk assessment responsibilities are scattered among various programs within dozens of federal agencies and programs. The same substance or technology is sometimes assessed differently by various agencies (e.g., EPA vs. OSHA).[45] Some agencies expose their assessments to external peer review while others do not.[46] If risk ranking becomes a more important factor in resource allocation within programs and among agencies, incentives for agency analysts to "game" the risk assessment process will be heightened — tactics that are difficult to manage in normal budgetary processes.

To stakeholders and the public, it may appear that no one is responsible for assuring scientific integrity and accountability in the federal government's risk assessment process. Of course, OSTP should not (and could not feasibly) undertake numerous risk assessments or even review every risk assessment report produced in the federal government. It is therefore important to clarify what leadership responsibilities can best be vested in a centralized risk-assessment function and what the processes of public participation and checks and balances should be.

First, uniform risk assessment guidelines applicable to all federal regulatory agencies need to be issued (and periodically updated) that are based on (a) using sound scientific data and qualified scientific judgments when they are obtainable, and (b) being transparent about the relative plausibility and policy implications of using alternative assumptions when science is incomplete or ambiguous. The guidelines should also include a new process where each regulatory agency proposes risk-based priorities on a periodic basis, taking into account the relative seriousness of risks in their jurisdiction and the available opportunities for cost-effective reduction of risk.

Given their broad applicability, these OSTP guidelines would be general in offering scientific content but more specific procedurally, thereby stimulating each agency or program to develop tailored guidelines that implement the letter and intent of OSTP's position in light of the agency's enabling statute. OSTP should review each agency's risk assessment guidelines and work with agencies to assure consistency with OSTP's position.

Second, OSTP should be authorized to review risk assessment determinations made by federal agencies. The purpose of review is to assure adherence to OSTP guidelines, a task that should be performed with the assistance of independent panels of qualified scientists. OSTP review should be reserved for assessments that satisfy specific criteria such as an assessment of a potential risk of major national or international significance (e.g., health concerns about electric and magnetic fields),

a new application of science with precedent-setting implications (e.g., chemicals that induce adverse health effects through a newly discovered biological mechanism), or a substance or technology of importance to multiple federal agencies (e.g., butadiene and wireless phones).

In cases where OSTP exercises its review authority, a risk-assessment determination should not represent the official position of the federal government until it is approved by both the drafting agency or agencies and OSTP. We envision that in some cases OSTP might withhold approval of an assessment until revisions are made based on the suggestions of qualified scientists, or until more collaboration is undertaken with scientists from multiple federal and state agencies. This new power for OSTP may initially be resisted by some agencies but we expect that OSTP's contributions will ultimately enhance the credibility of agency assessments and decisions.

By creating this new process of OSTP oversight of risk assessment activities, we expect that the impetus for judicial review of agency risk-assessment determinations will be reduced. This is an attractive result because federal courts generally lack the technical expertise to be effective participants in the resolution of risk assessment disputes. If both the line agency and OSTP, after public participation and peer review by the external scientific community, support a particular risk assessment determination, it is unlikely that a federal court would be inclined to overturn it, barring serious procedural irregularities.

Third, OSTP should initiate a three-year experimental effort, in collaboration with interested agencies, to rank a sizeable number of diverse risks (including risk-reduction opportunities) across the jurisdictions of different federal agencies. The experiment would build on the careful use of science and citizen participation that has characterized several "comparative-risk" projects in states such as Vermont and Washington. An experiment to examine diverse risks is necessary because important complexities in risk comparison need to be worked out: situations where the degree of uncertainty in two risk estimates differs, where the particular populations at risk differ in size and demographic composition, where the disease or ecological endpoints differ, where the degree of irreversibility of the effects differs, or where ordinary citizens have a different perspective than experts about the two hazards.

Thus, the purpose of this experiment is to learn how diverse risks should be compared, how ordinary citizens should participate in risk ranking, what the inherent limitations to the process might be, and how guidelines can be developed to govern a broad-based process of risk-based priority setting in the federal government. In particular, OSTP and agencies should work together to develop credible risk metrics that could be used in the more flexible risk-management plans discussed below in Recommendation #3. Based on this experiment, OSTP should report to Congress about how information from risk rankings should be used by Congress, OMB, and agencies in the annual development of budgetary priorities and the reauthorization or revision of enabling laws.

Fourth, OSTP should periodically survey the research priorities of the federal government to determine whether the data and methods required for sound risk assessment and risk ranking are being developed. Every three years OSTP should report to Congress on the direction of federally-supported research and how it could be strengthened to further the national goal of establishing risk-based priorities.

Finally, OSTP, in collaboration with the State Department and affected agencies, should provide the scientific expertise for negotiators from the United States in international discussions where risk assessment is a major issue. OSTP should also promote use of the principles of risk assessment and risk-based priorities by international organizations and treaties dedicated to protecting human health, safety, and the environment.

Some have proposed placing this authority in the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB-OIRA), a different unit within the Executive Office of the President that already has responsibility for reviewing rulemaking proposals prepared by agencies under the laws passed by Congress. The idea of granting OMB more power over risk assessment is worthy of consideration, particularly if OMB-OIRA's expertise in risk analysis and related scientific fields is buttressed. However, there is also virtue in separating OMB's review of rulemaking proposals from review of the earlier process of risk assessment. In particular, it would be preferable for OSTP to resolve with agencies what science does and does not know about risk before broader risk-management questions are reviewed by economists and policy analysts at OMB. Otherwise, suspicions could arise that OMB is forcing agencies to manipulate risk assessments in order to promote OMB's risk-management preferences. Given OMB's historical role in regulatory review, we believe scientific accountability would be better assured through OSTP leadership of risk assessments.

In making this recommendation, we are not suggesting that OSTP is currently capable, with existing expertise and resources, of carrying out the responsibilities described above. If Congress takes the step we are recommending, it will be making a long-term commitment to OSTP leadership in this area. Congress should appropriate funds for a team of well-trained and experienced risk analysts, led by a respected Director of Risk Analysis, to perform the functions described above. Creation of this entity in OSTP will also strengthen the stature and visibility of agency risk assessors throughout the federal government, since an institutionalized voice for risk assessment will be created in the Executive Office of the President.

In conclusion, we recognize that it is not desirable for Congress to prescribe in law an organizational arrangement that the President would find inflexible. On the other hand, it is crucial for Congress to authorize the President to undertake the specific responsibilities described above in a forum where science is respected but political accountability is also assured. While the White House may seek to avoid some of the political accountability that we are assigning to OSTP, our proposal makes it very clear who is in charge of risk assessment in the federal government and who should be held accountable by Congress and the public.

RECOMMENDATION #2: Congress should require regulators to achieve a reasonable relationship between costs and benefits when regulating risks.

Congress should pass omnibus legislation requiring that all federal agencies achieve a reasonable relationship between the incremental costs and the incremental benefits of new or revised rules aimed at protecting public health, safety, and the

environment. When determining what investments in risk reduction are reasonable, regulators should take into account quantitative estimates of benefit and cost (including the uncertainties in these estimates), intangible or qualitative benefits and costs, the distribution of benefits and costs among citizens, and the values of ordinary citizens as determined through a variety of mechanisms (e.g., public hearings, citizen panels, and social science research).

DISCUSSION

Many of the existing enabling statutes covering risks were passed on the heels of emotionally charged situations. The Superfund law was passed after the controversy surrounding chemical contamination in Love Canal, New York. The Emergency Planning and Community Right to Know Act and the Clean Air Act Amendments of 1990 were influenced by the Bhopal disaster in India. The Oil Pollution Act promptly followed the Valdez oil spill in Alaska.

When laws were drafted in such emotional settings, Congress did not enact provisions requiring agencies to achieve a reasonable balance between the benefits and costs of regulatory action. Thus, it is now appropriate for Congress to reassert the common sense principle that a regulation's anticipated benefits should bear a reasonable relationship to costs. Presidents Carter, Reagan, Bush, and Clinton have all embraced this basic philosophy in their executive orders on regulatory review. Better risk assessment (as described under Recommendation #1 above), coupled with a uniform requirement for reasonable balancing of costs and benefits, should promote a more cost-effective allocation of national resources.

In suggesting a uniform legal standard for federal risk management, we should clarify how this standard differs from one under which benefits must be shown to exceed costs, the strict net-benefit formulation. Our proposed standard goes beyond a requirement to simply consider benefits and costs, since it adds the substantive requirement that the relationship be reasonable. By choosing the words "reasonable relationship" rather than the word "exceed", Congress will be recognizing that, given the current science of risk analysis and cost-benefit analysis, it is not feasible to quantify and express in dollars all of the costs and benefits of risk regulations. Major progress has been made since the early 1980's in our technical ability to perform such analyses,[47] but our ability to predict, quantify, and monetize the value of certain environmental resources (e.g., future groundwater contamination) is still quite primitive.

When all of the issues at stake in regulation are ranked along a single scale (e.g., dollars), the analysis can be improved because it is made more systematic; but the analysis can simultaneously be impaired because the diverse outcomes at stake might best be seen for themselves, rather than be converted into a unitary scale. For example, some of the goods involved in environmental policy — aesthetic values, the quality of life in a community, ecological values, health values, and distributional concerns — are qualitatively diverse, and should be allowed to be expressed as such. This point does not mean that cost-benefit analysis should not be undertaken, but it does mean that any good cost-benefit analysis should offer a disaggregated as well

as monetized picture of the goods at stake.

As we noted earlier, regulatory judgments should go beyond a calculus of lives saved or lost and reflect deliberative judgements about factors such as whether risks are controllable by individuals through personal action, are faced by future and/or current generations, are potentially irreversible or catastrophic, and are equitably distributed in society. In the jargon of cost-benefit analysis, these considerations are sometimes called "intangible" or "psychic" factors.[48]

Hence, the more flexible wording we recommend allows regulators to address factors other than numerical net benefits that might act in favor of or against a proposed rule. Congress should apply this legal standard uniformly to all enabling risk-regulation statutes, in effect incorporating this new standard into all current laws.

Some might argue that technology-based requirements mandated in previous legislation should not necessarily be overridden by omnibus legislation, since Congress may have considered costs and benefits when these laws were passed.[49] Some degree of cost consideration is usually contained in technology-based requirements (e.g., the "feasibility" test in the Occupational Safety and Health Act and the various cost tests in the Clean Water Act). Congress could insulate technology-based requirements from the new "reasonable relationship" standard by retaining existing technology-based tests, but we believe a uniform risk management standard is preferable because of the need to consider benefits as well as costs.

Alternatively, Congress could review each provision in laws on a case-by-case basis when the enabling law is scheduled for reauthorization in Congress. At that point, Congress would be in a position to assess, based on historical experience, whether rules are achieving a reasonable relationship between costs and benefits. If not, the reasonable relationship test could then be inserted in place of existing requirements. However, since some statutes do not require authorization and others are rarely reauthorized, and since fragmentation of Committee responsibilities discourages uniform treatment, it is preferable for Congress to pass a uniform standard in a broad-based risk bill.

The extent of judicial review becomes an important consideration when a new statutory test is enacted. Our suggestion is that agency compliance with the new standard be reviewed by courts under the standard provisions of the Administrative Procedures Act and the existing judicial review provisions of enabling statutes. These statutes adopt the "arbitrary and capricious test" that accords considerable deference to the judgments of administrative agencies. If Congress seeks to further limit judicial review, they could narrow the power of judges to overturn agency decisions by requiring "clear and convincing evidence" that the agency's position is untenable.

A uniform legal standard in risk management would also bring more clarity and consistency to OMB's role in the regulatory review process. For example, the Clinton Administration's 1993 executive order on regulatory planning does require cost-benefit analysis of major rules, but only where the underlying statute passed by Congress does not prohibit benefit-cost balancing. Under the uniform legal standard we propose, agencies would have no legal avenue to avoid making a reasoned benefit-cost justification.

As a practical matter, agencies and OMB may often consider informally the benefits and costs of a major rule, even when a strict reading of the statute precludes such consideration. However, the public justification of resulting rules is often couched by agency lawyers in ways that mask any suggestion that cost-benefit balancing has occurred. This kind of behavior breeds cynicism about the regulatory process. It also undercuts the ability of affected parties to participate effectively in discussions about whether costs are reasonably related to benefits. Moreover, the value of civic education that is advanced by public rulemakings is undermined when statutes include implausible restrictions on the factors that may be considered or weighed by regulators.[50] Since all sound risk regulations should reflect a reasonable balance of benefits and costs, Congress should write statutes that permit such considerations to be discussed openly with the public.[51]

In suggesting that regulatory costs as well as benefits be considered, we are not implying that costs will uniformly be given more weight in decisions than under existing law. When agencies prepare cost estimates and expose such information to formal peer review and public scrutiny, it will become apparent whether cost estimates have been inflated to serve the interests of regulatees. In the long run, this scrutiny about the actual costs of regulation may lead to more measured claims about costs, thereby operating in favor of some rules that might otherwise be falsely rejected behind closed doors in the face of exaggerated claims about costs. Moreover, many existing laws (e.g., those that mandate technology-based standards) do not give much consideration to benefits. If Congress insists that both benefits and costs be weighed in rulemaking, that will provide impetus for more inquiry into how to identify, quantify, and weigh health, safety, and environmental values.

RECOMMENDATION #3: Congress should provide flexibility for federal regulators to approve plans submitted by regulatees that promise equal or more overall risk reduction than would result from strict compliance with federal regulations.

Congress should pass legislation authorizing flexibility to federal agencies to approve risk-management plans submitted by regulatees (i.e., individuals, private firms, and states and localities) that promise equal or greater reduction of risk than would result from compliance with existing laws and regulations. Agencies would assume the responsibility to certify whether or not the alternative plans submitted by regulatees are viable substitutes, based on a comparative analysis of risk reduction. If approved, the implementation of alternative plans should be monitored by regulatees and agencies to assure that the reductions of risk promised in alternative plans are achieved in practice. This recommendation is aimed at harnessing the creative energies of entrepreneurship in the service of cost-effective risk reduction.

DISCUSSION

In a rare yet encouraging partnership between government and industry, EPA and the Amoco Corporation recently completed a pollution-prevention project at a

refinery in Yorktown, Virginia. A team of scientists from EPA and Amoco, in collaboration with a peer review panel established by Resources for the Future, identified numerous ways that the refinery could simultaneously reduce pollution and reduce environmental compliance costs.[52] Unfortunately, the project concluded that the current patchwork of uncoordinated laws covering air, water, land, and waste disposal actually discourages (and in some cases prohibits) cost-effective efforts at pollution prevention.[53]

Another example of the need for flexibility is the Superfund program, where sensible and innovative solutions are often complicated or outlawed by an overly prescriptive statute. EPA has already recognized this problem to some extent in its Superfund Innovative Technology Evaluation (SITE) program. For example, the redevelopment of abandoned sites in urban areas can offer enormous economic progress for a community but may be blocked by mandatory treatment technologies, unrealistic cleanup standards, and strict liability rules. The risks reduced by complex and expensive remediation technologies are not necessarily the highest priority risks in the eyes of communities near an abandoned waste site.[54] More discretion should be provided to communities to propose creative solutions.

Voluntary industrial programs aimed at reducing toxic emissions into the environment could also be strengthened if EPA's Toxic Release Inventory data could be reported in a more flexible fashion than the current mass emission system. For example, under EPA's voluntary pollution prevention programs,[55] a firm should be allowed to report progress toward reducing chemical emissions using a system that gives more weight to more toxic pollutants or to pollutants that are known with greater certainty to cause human health or ecological effects. This kind of flexibility would be expected to produce more risk reduction while increasing the range of control options available to industrial risk managers (e.g., a firm might be permitted to increase emissions of a relatively harmless chemical by 10 pounds in exchange for a 5 pound reduction in emissions of a highly toxic or persistent pollutant — as long as the overall amount of predicted risk is the same or less).

As these examples illustrate, Congress should authorize agencies to grant regulatees flexibility to propose alternative risk-management plans that would have superior outcomes (i.e., equal or lower overall predicted risks) than would result from strict adherence to federal law and regulation. In effect, the federal government should set broad risk-management goals but leave regulated entities (states and localities as well as private firms) the flexibility to find and implement innovative solutions. Unlike current federal policy, which often blocks or discourages innovation in risk management, this policy is in favor of more flexible and creative approaches to risk management. It would mobilize the creative energies of entrepreneurship in the service of risk reduction, building on the promise of incentive-based policies,[56] including the success of allowance trading in removing lead from gasoline in the early 1970s and the experience with acid rain control under the Clean Air Act Amendments of 1990.

In authorizing such flexibility in risk management under federal supervision, Congress would create considerably more management options for firms faced with rapidly increasing marginal costs of pollution reduction and prevention. For

example, a regulatee would be empowered to propose new and different technologies for reducing the same pollutant or the same type of risk that is targeted by a federal regulation. In the EPA-Amoco example, a different emission control plan, one that was far less expensive, was available that would have reduced benzene and other emissions by a greater amount than is required under federal laws. Alternatively, a factory might propose to purchase older cars that are more significant sources of pollutants in a community.[57] The buy-back plan covering older cars should be approved if it is less expensive to the firm and promises equal or more overall risk reduction (considering the effects of all pollutants) than would result from the federal regulatory approach.

When authorizing flexibility, Congress should require regulators to evaluate alternative plans carefully and monitor the regulatee's progress in meeting its risk-reduction commitments. When evaluating plans, issues will be raised about whether alternative risk-reduction plans are supported by sufficient scientific and engineering information and whether the measures proposed are conducive to effective oversight and enforcement by the federal or state regulator. It will therefore be important for the federal government to have strong capabilities in risk assessment (as proposed above in Recommendation #1).

If excessive subjectivity is introduced into the comparison of plans, the process may lose credibility, which argues in favor of a constrained form of flexibility. Cases may arise where the risks to be compared differ in their nature, in the certainty of scientific evidence of hazard, in the affected subpopulations, in whether the risks are voluntary or involuntary, and in the disease or endpoint that may be affected. Regulatory judgments about comparability will become less subjective and more credible if the research proposed under Recommendation #1 determines that citizen values would actually support tradeoffs involving diverse risks.

Regardless of the precise degree of flexibility provided, which will in many cases require new legislation, we recommend that Congress insist that regulators monitor the performance of regulatees and hold them to their risk-management commitments. Given the promise of risk-management flexibility but the government's limited experience in monitoring such activities, we recommend that Congress proceed cautiously with a limited program of flexibility for regulatees. If this experiment proves successful, Congress should consider even more ambitious programs of "environmental contracting" that are now becoming commonplace in the Netherlands.[58]

RECOMMENDATION #4: Congress should transfer selected risk-management powers from the federal government to state and local authorities in order to determine whether decentralization would achieve more creativity, efficiency, and responsiveness to citizen values.

Congress should transfer selected risk-management powers (e.g., goal-setting and implementation authority under the Safe Drinking Water Act and certain aspects of the Superfund program) to state and local governments in situations where the costs and benefits of risk management are incurred by citizens within a specific state or

locality. This policy experiment should be evaluated carefully by Congress to determine whether states and localities devise policies that are more efficient, equitable, and democratic than has been experienced under existing federal law. Congress should monitor and review the results of this experiment to determine whether more large-scale decentralization of risk-management authority is appropriate.

DISCUSSION

Our review of federal risk regulation suggests that Congress has not always drawn a carefully considered distinction between a risk that should be regulated by the federal government and a risk that should be regulated by state and local authorities. By failing to draw this distinction, Congress has spawned some regulatory programs that may not be as efficient and responsive to citizen values as is appropriate. Moreover, by insisting on uniform federal policies in this complex area, we are missing the opportunity to learn from the numerous experiments in risk management that could be undertaken by state and local officials.

In suggesting an experiment in decentralization of some programs, we are aware of the powerful rationales that have been advanced for a strong federal role in risk management. When activities occurring in one state create significant risks (or costs) for citizens in another state or outside the United States, a presumptive role for the federal government is created. Examples would be the long range transport of air pollutants from the Midwest to the East, pollution of interstate bodies of water, and the potential role of U.S. pollutants in producing global warming. When the risk is created by a product sold across state lines, a presumptive role is created for the federal government (since it is inefficient for businesses manufacturing and distributing products to be confronted with conflicting risk regulations in various states). Examples are sales of a drug by national pharmaceutical companies to hospitals and physicians in several states and sales of gasoline by national companies to service stations in numerous states. Other rationales for federal involvement include lack of state and local expertise in risk management, concern that states and localities will not protect the health and safety of low-income and minority populations, concern about amenities of national importance (e.g., the Grand Canyon) and endangered species, and fears that some states will allow excessive amounts of pollution as they compete with other states for jobs and industry.

As powerful as these rationales may be, we propose that Congress consider, on a case-by-case basis, whether specific risk-management functions are best handled by the federal government. As an experiment in decentralization, we recommend that Congress consider shifting many existing risk-management functions from the federal government to the states and localities, including specifically the following:

- the setting of drinking water standards under the Safe Drinking Water Act while maintaining federal guidance based on the science of risk assessment;
- the setting of residual-risk goals for hazardous air pollutants under the Clean Air Act, again in conjunction with federal guidance; and

- the cleanup of local Superfund sites (i.e., those that do not pose problems of interstate migration of pollutants) and the selection of "corrective action" plans for facilities under the Resource Conservation and Recovery Act.

In each of these cases, the potential costs and benefits of the contemplated federal rules of conduct will be experienced primarily or exclusively by citizens residing within a particular state or locality. The citizens in these communities are probably in a better position than Congress or federal regulators to decide how safe is safe enough, as long as the federal government provides the scientific information about risk.

Our prediction is that states and localities will often perform better than the federal government measured by the yardsticks of effectiveness, efficiency and equity in risk management. Many states have much more capability in this area than they possessed twenty years ago, and most governors and mayors, while certainly attracted to economic development, would not be inclined to create serious pollution problems for their constituents. Moreover, if current political trends continue, many state governments may prove to be at least as sensitive to environmental and civil rights concerns as the federal government proves to be.

Congress should address this issue as key statutes are scheduled for reauthorization or revision. If Congress chooses to experiment with decentralization, we recommend that they set in place rigorous evaluation programs to determine how states perform on critical dimensions such as risk reduction, cost, equity, and responsiveness to citizen values. On the basis of such information, future legislators will be in a sound position to decide whether a more aggressive program of decentralization is appropriate.

APPENDIX: Supplementary Statements of Individual Members

Frederick Andersen

Our first recommendation stresses the importance of accountable, open risk assessment processes. To achieve these important goals, I believe that the new legislation should spell out the steps agencies must take to solicit and respond in writing to relevant comments on proposed agency risk assessments by other federal agency experts, state and local experts, the scientific community, and the public at large. This comment process would also go a long way toward creating the ad hoc peer review that is most appropriate to the proposed risk assessment, without the need for a new bureaucracy of special expert panels appointed by the agency. Some may object that because OSTP is located within the Executive Office of the President, like OMB it is vulnerable to political pressure by special interests with White House access. This is why it is important to specify, by statute, the comment processes set out above. Thus, and perhaps paradoxically, the unit of the Executive Branch that is often thought to be vulnerable to behind-the-scenes manipulation can become a strong instrument for the scientific integrity, transparency, and public access that federal risk assessment currently lacks.

Baruch Fischhoff

Our report offers an empirical analysis of the current state of risk management in the United States and a logical analysis of its desired state. Being neither a risk analyst, nor an economist, nor a lawyer, I am not in a position to review critically these empirical claims. Nonetheless, the issues that they raise clearly belong in any thoughtful review of our collective experience with risk over the last quarter century. As a psychologist, methodologist, and decision theorist, I can, however, offer my support to the general principles endorsed in the recommendations. They express commitments to a broad definition of public values (not restricted to readily quantifiable health and economic effects), to full disclosure of analytical assumptions and uncertainties (for risk and benefit estimates), to providing incentives for risk reduction, and to recognizing diverse and dispersed sources of expertise. Realizing the potential in these principles will require both skill and good will. Without it, reforms may backfire in a morass of paperwork misallocated analytical resources. Goodwill is needed to resist the temptation to rig the rules of analysis in order to achieve narrow political and economic ends. Without it, we will miss the chance to achieve a broad consensus on risk management — and, in the process, blacken the name of risk analysis (and risk analysts) as tools in the hands of the powerful.

Sheila Jasanoff

I interpret this report and its recommendations as an effort to enhance the fairness, transparency, efficiency, and scientific plausibility of risk regulation without introducing new institutional bottlenecks or compromising publicly legitimated objectives of health, safety, and environmental protection. To these ends, I endorse the concept of increased presidential oversight of risk analysis, but I firmly believe that, in order to maintain balance and independence, any such function must be lodged in an institutional context other than OMB-OIRA, such as an appropriately strengthened OSTP. The report, in my view, correctly stresses the need to combine the search for sound scientific approaches with a recognition of the limits of formal risk analysis and cost-benefit analysis as decision-making tools. Because of the indeterminacy of knowledge, and the need to respect non-scientific values such as equity, risk assessment oversight calls for expertise to be tempered with wisdom and judgement. It cannot be a purely scientific exercise. I construe the move toward increased oversight recommended in this report as a means of opening up the value components of technical analysis to more effective public review and control, not as a means of delegating political choices to unreviewable experts.

Charles W. Powers

My strong support of recommendations 1, 3 and 4 of this report (a central place where federal risk evaluation is integrated and overseen, freedom to allow the regulated community to devise and implement more effective ways of achieving regulatory goals, and an enhanced role for states, particularly on selected issues) have led me to endorse the full set of proposals despite some reservations about the wording of recommendation 2 (recommending that regulations achieve a reasonable

relationship between cost and benefits). Had the federal government followed the lead of sage participants and policy makers (including EPA administrators from both parties) on these issues, the federal risk administration process would long ago have been improved and rendered current criticisms less potent. I would have preferred a formulation of recommendation 2 (on cost-benefit) that even more strongly recognizes that the metric for cost analysis, not just benefits, is itself in such flux that we should continue to give the presumption to regulatory benefits where we are quite uncertain as to outcomes. Hence, the burden in any regulatory proceeding or judicial review should always fall on those who assert that the costs of any proposed rule do outweigh benefits.

Richard Stewart

I do not believe that our recommended program of risk management flexibility (Recommendation #3) should be in some undefined fashion be "limited". The Group properly insists that alternative risk management plans should be carefully examined and monitored by regulators and that there should be appropriate assurances that the commitments made therein are met. So long as these requisites are satisfied, I see no reason why the availability of this option and its benefits to the public should be artificially restricted.

Rae Zimmerman

I would like to emphasize how the conditions of implementation will influence the viability of the Group's recommendations about cost-benefit balancing, delegation of authority to states, and making use of risk comparisons. The Group's recommendations, when used, should be accompanied by specific conditions of implementation to avoid increasing regulatory complexity rather than decreasing it. Cost-benefit analysis is well-defined in some areas, but in environmental regulation serious limitations could question its use entirely, for example, the difficulty of valuing human lives and aesthetic values. The use of cost-benefit analysis will also require addressing major problems of definition of both costs and scope. Moreover, legal issues regarding its use will arise, such as liability for injury and death where a protective action was considered too costly to be undertaken. Thus, the use of cost-benefit analysis should be accompanied by conditions for its use and management options where it cannot be used. Before programs can be effectively delegated to local government, questions of resources, equity, and competence will have to be addressed. Some of these issues may be serious enough to make delegation to local government impossible. Valid risk comparisons require comparable and relevant exposure conditions (e.g., exposure routes and population sensitivities). Where such conditions are not met, adjustments should be made prior to comparing risks.

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